K062617

SPECIAL 510(k) SUMMARY for the modification to Inion OTPS™ Biodegradable Fixation System (K030900)

OCT - 4 2006

MANUFACTURER

Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person

Kati Marttinen, Regulatory Affairs Specialist
Lääkärinkatu 2, FIN-33520 Tampere
Phone: +358 3 2306 600
Fax: +358 3 2306 691
kati.marttinen@inion.com

DEVICE NAME

Trade name: Inion OTPS™ Biodegradable Fixation System
Common/Usual Name: Biodegradable bone screw
Classification Name: bone fixation screw

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification panel: Orthopedic
Regulation number: 21 CFR 888.3040
Regulation name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC

PREDICATE DEVICE

Inion OTPS™ Biodegradable Fixation System (K030900)

CONFORMANCE WITH PERFORMANCE STANDARDS

No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The modified Inion OTPS™ Biodegradable Fixation system implants are identical to the currently cleared devices except for the modifications which have been detailed in section 3 of this submission.

Inion OTPS™ Biodegradable Fixation System implants are made of resorbable polylactic acid / trimethylenecarbonate copolymers. Inion OTPS™ Biodegradable Fixation System implants gradually lose their strength during 18-36 weeks in vivo with complete strength loss and resorption within two to four years.

Indications

Inion OTPS™ Biodegradable Fixation system screws are generally intended for maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.
Specific indications:

- Fractures and osteotomies of the malleoli
- Ankle fractures

EQUIVALENCE TO MARKETED PRODUCTS

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation profile and mechanical properties of the modified Inion OTPS™ Biodegradable Fixation system screws are substantially equivalent with the predicate device Inion OTPS™ Biodegradable Fixation system (K030900).

The modified Inion OTPS™ Biodegradable Fixation system screws are substantially equivalent to predicate Class II devices used for maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization, because the differences between the modified Inion OTPS™ Biodegradable Fixation system screws and the predicate device do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2006

Inion Ltd
c/o Ms. Kati Marttinen
Regulatory Affairs Specialist
Lääkärinkatu 2,
FIN-33520
Tampere, Finland

Re: K062617
Trade/Device Name: Inion OTPS™ Biodegradable Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 31, 2006
Received: September 5, 2006

Dear Ms. Marttinen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K062617

Device Name: Inion OTPS™ Biodegradable Fixation System

Indications:

A. General indications: These **INION OTPS™ BIODEGRADABLE FIXATION SYSTEM** implants are generally intended for maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.

B. Specific indications:

- Fractures and osteotomies of the malleoli
- Ankle fractures

Contraindications:

These **INION OTPS™ BIODEGRADABLE FIXATION SYSTEM** implants are not intended for use in and are contraindicated for:

- Active or potential infection.
- Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse).
- High-load bearing applications.

Prescription Use (Part 21 CFR 801 Subpart D)	Yes	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C) No

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062617